JUN - 6 2003 **510(k) Summary**

K031165

Date
April 10, 2003

Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA 92121

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Cemented Hip Stem

Classification name
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
(per 21 CFR section 888.3350)

Equivalent Device
This cemented hip stem is equivalent in design, materials, strength and indications to the Consensus Stem (K922561 - Hayes Medical), the Foundation Hip (K991227 - Encore Orthopedics), the Synergy stem (K990369 - Smith & Nephew) and the Summit stem (K013352 - J&J/DePuy).

Device Description
This is a cemented hip stem fabricated from forged cobalt-chromium-molybdenum alloy (CoCrMo) that conforms to ASTM F799. It has a trapezoidal proximal body cross section, tapering both lateral to medial and proximal to distal. The proximal body has a cobra flange along the lateral aspect that helps to apply compressive stresses to the cement. It has a "standard 12/14" Morse type taper to accept modular heads and a neck/shaft angle of 129°. It also has a calcar collar that extends medially only.

The distal stem is conical in shape, tapering proximal to distal. At the distal end the stem quickly necks down to accept a PMMA distal centralizer. This centralizer is four flanged and is utilized to assure that the distal stem is centered in the femoral canal and a uniform cement mantle is obtained. The distal stem has four flutes or grooves that increases torsion stability when implanted in cement.

Shallow holes are drilled into the proximal body into which 3m PMMA spacers are pressed. These spacers assure a 3mm cement mantle around the medial, anterior and posterior surfaces.

Intended Use
The PLUS Orthopedics Cemented Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head has been subject to disease or trauma. It is also intended to treat previously failed hip arthroplasties. This device is intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Summary Nonclinical Tests
Engineering analysis indicates that this stem will withstand cyclic loads similar to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

PLUS Orthopedics
c/o Mr. J.D. Webb
Authorized Contact Person
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K031165
Trade/Device Name: Plus Orthopedics Cemented Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: April 10, 2003
Received: April 14, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K031165

Device Name: PLUS Orthopedics Cemented Hip Stem

Indications for Use:

Cemented Hip Stem
Indications for Use

The PLUS Orthopedics Cemented Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head has been subject to disease or trauma. It is also intended to treat previously failed hip arthroplasties. This device is intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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